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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/730,606	12/08/2003	Patrick J. Sweeney	029815-0105	4015
26371 7590 02/17/2009 FOLEY & LARDNER LLP 777 EAST WISCONSIN AVENUE MILWAUKEE, WI 53202-5306			EXAMINER STEWART, ALVIN J	
			ART UNIT 3774	PAPER NUMBER
			MAIL DATE 02/17/2009	DELIVERY MODE PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No. 10/730,606	Applicant(s) SWEENEY, PATRICK J.	
	Examiner Alvin J. Stewart	Art Unit 3774	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 24 December 2008.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 19-23 and 42-75 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 19-23 and 42-75 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☒ The drawing(s) filed on 08 December 2003 is/are: a) ☒ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413) |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | Paper No(s)/Mail Date. _____ |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08) | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| Paper No(s)/Mail Date _____ | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

Response to Arguments

Applicant's arguments filed 12/24/08 have been fully considered but they are not persuasive.

After a careful examination of the Applicant's arguments and the review of the interview conducted on November 26, 2008, at the time of the interview, the Examiner thought that the new limitations would overcome the prior art but after a careful examination of the limitations the Examiner believes that the prior art still reads on the new limitations of the claims after a new approach made by the Examiner (shown below).

Regarding claims 19-23, 42-51, 52-59, 60-74 and 75, the examiner still believes that the 103 rejection made by the Muhlhausler et al US Patent 6,524,342 (from this point is the '342 patent) patent is proper. The Applicant's representative argues that the '342 patent design is not capable of removing the shaft 10 from the patient without removing both the body and the head because as shown in Figures 1 and 2 the head 40 has to be removed from the neck 32 in order to insert a tool through aperture 34 and remove shaft 10. Nowhere in the specification disclose the above, however, the Examiner believes that what the Applicant's representative disclose it might be true. However, the Examiner wants to point out that the above language phrase "removing the shaft...." is broad enough that the Examiner can interpret the above language as follow: the Applicant's representative has not positively claimed the location from where the head and the body are not removed. The Examiner believes that the '342 reference is capable of reading the claimed language because if the head is dislodged from the neck 32 and held inside the patient's

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body, then the shaft 10 can be removed from the patient without removing the body 30 and the head 40 from inside the patient's body.

Regarding the Dwyer reference, the Examiner still believes that the rejection is proper. For example, element 14 is capable of being held inside the patient's intramedullary canal while element 12 is dislodged from the shaft 18 and the head 16. When the head 16 is dislodged from element 12 the head is capable of been held inside the patient's body while element 12 and element 18 are removed. For the above reasons the examiner believes that the previous rejection is proper.

NOTE: the Examiner wants to point out that there are additional ways that the examiner can interpret the claims and the prior art.

Finally, the Examiner added a new rejection with respect to independent claim 19 if the Applicant's representative tries to add new limitations to the claim claiming that the head and the body are all the time connected with each other while the shaft is removed.

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(e) the invention was described in (1) an application for patent, published under section 122(b), by another filed in the United States before the invention by the applicant for patent or (2) a patent granted on an application for patent by another filed in the United States before the invention by the applicant for patent, except that an international application filed under the treaty defined in section 351(a) shall have the effects for purposes of this subsection of an application filed in the United States only if the international application designated the United States and was published under Article 21(2) of such treaty in the English language.

Claims 42-48, 50, 52-56, 58-65, 67-69, 73, and 74 are rejected under 35 U.S.C. 102(e) as being anticipated by Dwyer et al US Patent 7,122,056.

Dwyer et al discloses an implant having a body (100) having a central canal (36) and coupled to an articular surface (ball connected to neck element 26, element 26 is connected to insert 12 and the other surface of the insert 12 is connected to the central canal (36) of body (14); a shaft (18) is coupled to the body and the shaft can be removed from the patient after implantation of the prosthesis without removing the body.

Additionally, the device is configured for replacing a hip joint or is capable of being inserted into a shoulder joint. Additionally, the shaft can be called a nail.

Finally, the modular joint of the Dwyer et al reference has a plurality of different shafts (18), see Figs. 1, 5, 6, 12A and 13 that are capable of being replaced in the embodiment of Figure 5. Also, if the shaft (18) of the embodiment of Figure 5 is damaged, the shaft (18) can be replaced by a new shaft.

Regarding claims 50, 51, 56, 57, element 48 is the insert.

Regarding claims 44, 45, 55, 63 and 64, see element 32 in Figure 5.

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

Claims 49, 51, 57, 66, 70-72 and 75 are rejected under 35 U.S.C. 103(a) as being unpatentable over Dwyer et al US Patent 7,122,056.

Dwyer et al discloses the invention substantially as claimed. However, Dwyer et al does not disclose a locking element configured to be screwed into the central canal to lock the first

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shaft in place and does not disclose a shaft removal device configured to remove the first shaft from the central canal.

Regarding the shaft removal, it would have been obvious to one having ordinary skill in the art at the time the invention was made to modify the Dwyer et al reference by using a delivering tool, such as a pliers, in order to insert or remove the prosthetic shaft.

The Dwyer et al is silent regarding the opening and closing of the access aperture, however, it is an inherent characteristic to open the patient's body in order to replace a damage joint and close the patient's body after the surgeon finished fixing the damaged joint.

Regarding the length of the first and second shafts, Dwyer et al discloses the claimed invention except for the teaching of having different shafts length. It would have been an obvious matter of design choice to have a plurality of modular shafts with different lengths, since such a modification would have involved a mere change in the size of a component. A change in size is generally recognized as being within the level of ordinary skill in the art. *In re Rose*, 105 USPQ 237 (CCPA 1955).

Regarding claims 51, 57, and 66, it would have been obvious to one having ordinary skill in the art at the time the invention was made to modify the taper interlock of element 12 with the taper cavity of element 14 by a threaded cavity with a threaded post in order to make a strong and fixed connection between two structures.

Claims 19-23, 42-51, 52-59, 60-74 and 75 are rejected under 35 U.S.C. 103(a) as being unpatentable over Muhlhausler et al 6,524,342 B1.

Muhlhausler et al discloses an implant having a body (30) having a central canal (34) and coupled to an articular surface; a shaft (10) is coupled to the body and the shaft can be removed

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from the patient after implantation of the prosthesis without removing the body and a locking element (20 or 15).

However, Muhlhausler et al does not disclose the step of creating an access aperture, removing a shaft and replaced it with a second shaft and closing the access aperture.

Regarding the opening and closing of the access aperture, it is an inherent characteristic of insertion of implant within the human body to create an access aperture before the implant is inserted and then closing the same aperture after the implantation is completed.

Regarding the removal of a shaft and replacement of a second shaft, the device is capable of being replaced by a second shaft without removing both the body and the head is required. The specification clearly disclose that the shaft can be loosened during operation in order to adjust the shaft length or the rotation position of the shaft, therefore, if necessary the shaft is capable of being replaced if the shaft is damage, or get loosened in the intramedullary canal or the patient needs a longer shaft.

It would have been obvious to one having ordinary skill in the art at the time the invention was made to modify the steps above for the purpose of replacing an old shaft by a new one.

Regarding claims 42-51; 52-59 & 60-74, Muhlhausler et al does not disclose a plurality of shafts. It would have been obvious to one having ordinary skill in the art at the time the invention was made to have a modular implant having a plurality of different shafts in order to select the appropriate shaft for each patient. Additionally, it would have been obvious to one having ordinary skill in the art at the time the invention was made to have a aplurality of

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different shafts capable of being replaced if the shaft is damaged, or get loosened in the intramedullary canal or the patient needs a longer shaft.

Regarding claims 44, 45, 55 & 63-64, it would have been obvious to one having ordinary skill in the art at the time the invention was made to modify the threaded connection of the shaft with the body with a Morse taper connection because at the time the invention was made, it would have been an obvious matter of design choice to a person of ordinary skill in the art to modify the threaded connection with the Morse taper connection because Applicant has not disclosed that by having a Morse taper connection provides an advantage, is used for a particular purpose, or solves a stated problem. One of ordinary skill in the art, furthermore, would have expected Applicant's invention to perform equally well with the threaded connection because it would perform equally as well.

Therefore, it would have been an obvious matter of design choice to modify Muhlhausler et al reference to obtain the invention as specified in claims 44 & 45.

Claims 19-23, and 42-75 are rejected under 35 U.S.C. 103(a) as being unpatentable over Muhlhausler et al 6,524,342 B1 in view of Dwyer et al US Patent 7,122,056 B2.

Muhlhausler et al discloses an implant having a body (30) having a central canal (34) and coupled to an articular surface; a shaft (10) is coupled to the body and the shaft can be removed from the patient after implantation of the prosthesis without removing the body and a locking element (20 or 15).

However, Muhlhausler et al does not disclose the step of creating an access aperture, removing a shaft and replaced it with a second shaft and closing the access aperture and is not capable of removing the shaft 10 without removing the head 40 from the body 30.

Dwyer et al discloses an implant having a body (100) having a central canal (36) and coupled to an articular surface (ball connected to neck element 26, element 26 is connected to insert 12 and the other surface of the insert 12 is connected to the central canal (36) of body (14); a shaft (18) is coupled to the body and the shaft can be removed from the patient after implantation of the prosthesis without removing the body.

Additionally, the device is configured for replacing a hip joint or is capable of being inserted into a shoulder joint. Additionally, the shaft can be called a nail.

It would have been obvious to one having ordinary skill in the art at the time the invention was made to modify the Muhlhausler et al reference by changing the oblong head with the oval head of the Dwyer et al reference in order to fit the prosthesis to an regular acetabular cup in a patient's hip.

Regarding the opening and closing of the access aperture, it is an inherent characteristic of insertion of implant within the human body to create an access aperture before the implant is inserted and then closing the same aperture after the implantation is completed.

Regarding the removal of a shaft and replacement of a second shaft, the device is capable of being replaced by a second shaft without removing both the body and the head is required. The specification clearly disclose that the shaft can be loosened during operation in order to adjust the shaft length or the rotation position of the shaft, therefore, if necessary the shaft is capable of being replaced if the shaft is damage, or get loosened in the intramedullary canal or the patient needs a longer shaft.

It would have been obvious to one having ordinary skill in the art at the time the invention was made to modify the steps above for the purpose of replacing an old shaft by a new one.

Regarding claims 42-51; 52-59 & 60-74, Muhlhausler et al does not disclose a plurality of shafts. It would have been obvious to one having ordinary skill in the art at the time the invention was made to have a modular implant having a plurality of different shafts in order to select the appropriate shaft for each patient. Additionally, it would have been obvious to one having ordinary skill in the art at the time the invention was made to have a plurality of different shafts capable of being replaced if the shaft is damaged, or get loosened in the intramedullary canal or the patient needs a longer shaft.

Regarding claims 44, 45, 55 & 63-64, it would have been obvious to one having ordinary skill in the art at the time the invention was made to modify the threaded connection of the shaft with the body with a Morse taper connection because at the time the invention was made, it would have been an obvious matter of design choice to a person of ordinary skill in the art to modify the threaded connection with the Morse taper connection because Applicant has not disclosed that by having a Morse taper connection provides an advantage, is used for a particular purpose, or solves a stated problem. One of ordinary skill in the art, furthermore, would have expected Applicant's invention to perform equally well with the threaded connection because it would perform equally as well.

Therefore, it would have been an obvious matter of design choice to modify Muhlhausler et al reference to obtain the invention as specified in claims 44 & 45.

Regarding the shaft removal, it would have been obvious to one having ordinary skill in the art at the time the invention was made to modify the Dwyer et al reference by using a delivering tool, such as a pliers, in order to insert or remove the prosthetic shaft.

Conclusion

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Alvin J. Stewart whose telephone number is 571-272-4760. The examiner can normally be reached on Monday-Friday 7:00AM-5:30PM(1 Friday B-week off).

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Dave Isabella can be reached on 571-272-4749. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/Alvin J Stewart/
Primary Examiner, Art Unit 3774

February 12, 2009.